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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,083	12/06/2001	John O. McWeeney	BSC-211	8839
21323	7590	02/24/2004		
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110				
			EXAMINER WILLSE, DAVID H	
			ART UNIT 3738	PAPER NUMBER 12

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/006,083

Applicant(s)

MCWEENEY, JOHN O.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al., US 5,876,445. The term “wound coil *portion*” (instant claim 22, line 3; emphasis added) can, for example, be viewed not as a complete coil but as a portion of a coil. Nevertheless, a wound coil form is taught at column 12, lines 41-45, and Figure 7o. As seen from column 4, lines 16-30, a valve or sphincter portion collapses under radial compressions so as to impede the flow of body fluid unless the internal body fluid pressure overcomes the compressive stresses or pressures. Such a valve device is provided in various diameters and lengths (e.g., Table 1) and, at least for some embodiments, is thus *capable* of being placed within an intramural tunnel portion of a ureter so as to extend into a bladder, whether or not such was the intent. Moreover, it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense (*In re Hutchison*, 69 USPQ 138). MPEP 2106, section II. C., explains that language which suggests or makes optional but “does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation”; “examples of language that may raise a

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question as to the limiting effect of the language in a claim” are “adapted to” and “adapted for” clauses. Regarding claims 23-25: column 8, lines 38-41; column 11, lines 52-54; column 14, lines 22-24. Regarding claim 26: column 9, lines 40-45.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al., US 5,876,445, which contemplates ureteral stents at column 8, lines 46-47. The device extending at least along the entire ureter would have been obvious from the fact that as urine collects in the pelvis of a kidney, a peristaltic contraction spreads downwardly along the ureter to force urine toward the bladder, and the Andersen et al. device possesses certain advantages with respect to peristalsis (column 1, lines 60-63; etc.). Official notice is taken that it is well known in the art to provide a ureteral stent with anchoring portions extending into the kidney and the bladder. To incorporate such into the Andersen et al. ureteral stent would have been obvious from their known, innate advantages, with the ordinary practitioner having been left to devise an appropriate structure and having been motivated by column 1, lines 60-63; column 3, lines 28-29; column 4, lines 10-11; etc. Because Andersen et al. teach that “[t]he stent could be shaped to include, in its free and rest states, a narrowing at a point in its length” so as to “accommodate the stent to the anatomy of a natural sphincteric structure” (column 9, lines 4-7), and because one of ordinary skill would have been aware of the fact that pressure in the bladder compresses the ureter so as to prevent backflow of urine when pressure builds up in the bladder during micturition, it would have been obvious to incorporate a collapsible narrowing at the corresponding location in the ureteral stent structure of Andersen et al. Regarding claims 7, 22, and others, J-shaped and pigtail or coiled anchoring portions were quite common in the art and

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would have been obvious from their known advantages pertaining to stability, fluid conveyance, etc.

The Applicant's remarks have been considered. In regard to the scope of the Applicant's claims, one portion of the stent being mesh does not preclude the other portions from being mesh, and there are at least four well-defined portions in the aforementioned ureteral stent embodiment obvious from Andersen et al., including opposite anchoring portions and a sphincter portion. Other issues are adequately addressed in the grounds of rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**